DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 22, 2014

Merit Medical Systems, Inc.
Siobhan King
Regulatory Affairs Specialist II
Parkmore Business Park West
Galway, Ireland

Re: K143429
Trade/Device Name: Passage Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, Or Fitting
Regulatory Class: Class II
Product Code: DTL
Dated: November 27, 2014
Received: December 1, 2014

Dear Ms. King,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143429

Device Name
Passage Hemostasis Valve

Indications for Use *(Describe)*
The Passage Hemostasis Valve is recommended for maintaining a fluid-tight seal around percutaneous transluminal angioplasty catheters and guidewires.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5
510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	Telephone Number:	(+353) 91 703700 (3061)
	Fax Number:	(+353) 91 703772
	Contact Person:	Mark Mullaney
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park West Galway, Ireland
	Telephone Number:	(+353) 91 703700 (3052)
	Fax Number:	(+353) 91 703772
	Contact Person:	Siobhan King
	Date of Preparation:	27/11/2014
	Registration Number:	9616662
Subject Device	Trade Name:	Passage
	Common/Usual Name:	Hemostasis Valve
	Classification Name:	21 CFR 870.4290 Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Predicate Device	**Primary Predicate Device #1:**	
	Trade Name:	Passage
	Classification Name:	21 CFR 870.4290 Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
	Premarket Notification:	K925419
	Manufacturer:	Merit Medical Systems, Inc.
	Reference Device #2:	
	Trade Name:	Rotating Adapter
	Classification Name:	21 CFR 870.4290 Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
	Premarket Notification:	K140475
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II 21 CFR 870.4290 Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass FDA Product Code: DTL Review Panel: Division of Cardiovascular Devices	

Intended Use	The Passage Hemostasis Valve is recommended for maintaining a fluid-tight seal around percutaneous transluminal angioplasty catheters and guidewires.
Device Description	The Passage Hemostasis Valve minimizes blood loss during diagnostic and interventional procedures. The Merit Passage Hemostasis Valve consists of a Y-adaptor with a hemostasis valve which also incorporates a female luer lock connector and a male luer lock rotator. The polycarbonate used to manufacture the adaptor is transparent to aid in visualizing entrapped air. The hemostatic valve adjusts between 0 to 0.097" (approximately 7 French). The Y-body design allows both injection of contrast and placement of interventional devices. The Passage Hemostasis Valve is comprised of a stand-alone rotator assembly bonded to the polycarbonate Y-body, using a UV cured adhesive. The seal and washer are inserted into the Y-body valve port. A thin coat of silicone is applied to the threaded portion of the Y-body and the cap is assembled. The standalone rotator assembly is comprised of individually molded polycarbonate parts(housing connector, retaining collar, hub) and an EPDM(Ethylene Propylene Diene Monomer) O-Ring.
Comparison to Predicate	The technological characteristics of the subject Merit Passage Hemostasis Valve are substantially equivalent to the Predicate Merit Passage Hemostasis Valve [K925419]. Both devices use the same components and materials, with the exception of the O-Ring, which has undergone a material change from silicone to EPDM. The device design and indications remain unchanged. The O-Ring material change was previously assessed under the Reference Device#2 Merit Rotating Adaptor, K140475.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit Passage Hemostasis Valve was conducted based on risk analysis. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. Where appropriate, the tests were based on the requirements of the following documents: • ISO 11070:1998, *Sterile Single-Use Intravascular Catheter Introducers.* • ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – part 2: Lock fittings • ISO 11135:2014 *Sterilization of health care products-Ethylene*

	oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices. • ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* • ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.
Safety & Performance Tests *continued*	The following is a list of all significant testing that was successfully completed: • Rotator Rotation • Compression Seal – Hemostasis Characteristics (low pressure) • High Pressure Capability (Maximum 200psi) • Air Ingress under Vacuum • Biocompatibility All test results were comparable to the predicate device and the subject Merit Passage Hemostasis Valve met the acceptance criteria applicable to the safety and effectiveness of the device. This has demonstrated the subject device is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject Merit Passage Hemostasis Valve is substantially equivalent to the predicate device, the cleared Merit Passage Hemostasis Valve, K925419, manufactured by Merit Medical Systems Inc.